K131906

Section 006 – 510(k) Summary (SMDA Requirements)

Additional Information – March 31, 2014

APR 1 1 2014

This Summary of Safety And Effectiveness is submitted in accordance with 21 CFR 807.92.c.

01 – Administrative Information

01- a. Date Prepared:	June 20, 2013
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01- e. Establishment registration number:	8044015

02 – Device Information

02-a. Trade Name of Device:	SCANWAVE PEN
02-b. Common Name of Device:	Ultraviolet Activator for Polymerization
02-c. Classification Regulation:	21 CFR 872.6070
02-d. Medical Device Class:	II
02-e. Panel:	Dental
02-f. Product Code:	EBZ

ISO 13485

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03 – Identification of Legally Marketed Predicate Device(s)

The Substantial Equivalence (SE) of SCANWAVE PEN is based on the Predicate Devices identified in the Table 01.

Table 01 – Identification of Legally Marketed Predicate Devices

Trade Name	Manufacturer	Product Code	510(k) number	Date Cleared
MINI LED AUTOFOCUS	SATELEC	EBZ	K072181	September 19, 2007
BLUEPHASE® 20i	IVOCLAR VIVADENT, Incorporated	EBZ	K091020	June 12, 2009

04 – Intended Use of SCANWAVE PEN

SCANWAVE PEN is a source of illumination for the polymerization of light-curing dental materials curing in the wavelength range of 390 nm - 505 nm.

05 – Description of SCANWAVE PEN

05-a. Scientific principles

The specific wavelengths of the light source activate the photo-initiators contained in the dental materials (resins). The activation of the photo-initiators produces the hardening of the dental material.

05-b. Principles of operation

SCANWAVE PEN is a Dental Curing Light. More precisely, SCANWAVE PEN is a source of illumination used for the polymerization of light-curing dental materials curing in the wavelength range of 390 nm - 505 nm. SCANWAVE PEN is equipped with LEDs (Light Emitting Diode) which permit to polymerize a large range of dental materials present on the market.

06 – Description of SCANWAVE PEN Design

SCANWAVE PEN is an Electro-medical Device. SCANWAVE PEN is compatible with only ADEC Dental units. The Handpiece contains the electronic command board, the power board and the light source. The optical guide is intended to transmit the light delivered by the Handpiece on the clinical site. The rigid protection shield fixed on the Handpiece reduces the light propagation of the curing Light. This accessory is used to protect the eyes of the patient and the user during the polymerization act. The O.E.M Module is a power supply module intended to deliver the electrical source needed for the Handpiece functioning's. The O.E.M Module is integrated in an ADEC dental unit. The Accompanying Documentation explains all needed information for a correct using (description, safety aspects, problems, cleaning, disinfecting and sterilization procedures).

07 – Identification of the Risk Analysis Method

The risks to health associated to SCANWANVE PEN are managed through the section n°7 of the Guidance Document named "*Dental Curing Lights – Premarket Notification [510(k)] Submission – March 27, 2006.* The Identified risks of the applicable Guidance Document are covered by several means of risk mitigation (design, EMC and Safety tests, Sterilization and biocompatibility tests, labeling, performance tests).

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08 – Description of the performance aspects

The Depth of Cure performed on Dental Materials (resins) is identified as the intended performances of SCANWAVE PEN. Comparison tests of Depth of Cure have been performed between SCANWAVE PEN and Predicate Devices. The obtained results show that the Depths of Cures of the SCANWAVE PEN are substantially equivalent and coherent with the claimed Intended Use.

09 – Intended Use of SCANWAVE PEN compared to the Predicate Device

Table 02 - Indication for Use Comparison

Trade / Device name	SCANWAVE PEN	Predicate Device n°1 MINILED AUTOFOCUS	Predicate Device n°2 BLUEPHASE® 20i
Intended Use	SCANWAVE PEN is a source of illumination for the polymerization of light-curing dental materials curing in the wavelength range of 390 nm - 505 nm.	The Satelec Mini LED AutoFocus is intended to be used by qualified dental practitioners as an ultraviolet activator for polymerization for: Photo-polymerization in the 420 - 480 nm waveband of visible light cured (VLC) dental materials. Photo polymerization in the 420 - 480 nm waveband of visible light cured (VLC) restorative composite materials, and Photo-polymerization in the 420 - 480 nm waveband of visible light cured (VLC) orthodontic brackets, and orthodontic bonding and sealing materials	For the polymerization of light-curing dental materials curing in the wavelength range of 380-515 nm.
Part	872 - Dental devices		
Regulation Number	21 CFR 872.6070		
Regulation Name	Ultraviolet Activator for Polymerization		
Regulatory Class	II		
Product Code	EBZ		

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10 – Technological characteristics of SCANWAVE PEN compared to the Predicate Devices

Table 03 – Technological characteristics and performances Comparison

	SCANWAVE PEN	Predicate Device n°1 MINILED AUTOFOCUS	Predicate Device n°2 BLUEPHASE® 20i
Handpiece Dimensions			
Overall Weight (g)	76	99	143
Overall Size (mm)	Ø 24 x 122		46 x 197
Light Sources			
Quantity / Source	4 LED	1 LED	4 LED
Range of Wavelength (nm)	390 to 505	420 to 480	385 to 515
Power Source			
Type	O.E.M Module		Main adapter
Input Voltage (VAC)	24		100-240
Output Voltage (DC)	5		
Handpiece Input Voltage			
Input Voltage (VDC)	5 V		3.7 - 5V
Safety Controls			
Safety Controls	Activation of a thermal sensor in case of overheating in the device (caused by an intensive using)		
Material			
Handpiece	Metallic Body (aluminum)		Plastic Body
Optical Guide	Glass and metallic part		Glass and plastic part
Optical Protector	Plastic		
Performance Specifications			
Typical Irradiance at 2 mm (mW/cm²)	1500	2200	2000 - 2200
Depth of Cure (mm) depending of dental Materials and Polymerization modes	0.5 to 4.5	1 to 3	0.5 to 4
Standards			
Safety & EMC Standard	IEC60601-1 / IEC60601-1-2		
Specific Standard for Dental Curing Light	ANSI / ADA Standard No. 48 - Visible Light Curing Unit – Part 2 – Light Emitting Diode (LED)		ANSI / ADA Specification No. 48, Visible Light Curing
Fire aspects	UL94-V0 for Printed Circuit Boards		Unknown
Biocompatibility	ISO 10993-1 and ISO 10993-5		Unknown

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Additional Information – March 31, 2014

11 - Determination of substantial equivalence

SCANWAVE PEN and Predicate Devices are identified as Ultraviolet Activators for Polymerization according to Classification Regulation n°21 CFR 872.6070 used for Dental Applications.

11-a. Indication for Use Perspective

SCANWAVE PEN Indications for Use are Substantially Equivalent to the Predicate Devices.

11-b. Design Perspective

In Design Perspective:

- SCANWAVE PEN and the Predicate Device n°1 are Substantially Equivalent in term of dimensions.
- SCANWAVE PEN and Predicate Devices are Substantially Equivalent in term of Light sources (LED light source).
- The SCANWAVE PEN and the Predicate Device n°1 are Substantially Equivalent in term of Operation Modes and Command.
- The SCANWAVE PEN and Predicate Devices are Substantially Equivalent in term of Power Source.
- The SCANWAVE PEN and Predicate Device n°1 are Substantially Equivalent in term of Design.

11-c. Material Perspective

In Material Perspective, the Substantial Equivalence document has defined that:

- The Material of SCANWAVE PEN and Predicate Device n°1 are identical.
- The Material potentially in direct contact with the patient of SCANWAVE PEN and Predicate Device n°1 are identical.

11-d. Discussion and conclusion of the non-clinical Tests

Polymerization performance:

The aim of the non clinical tests (on test bench) was to demonstrate the Substantial Equivalence of the SCANWAVE PEN and the selected Predicate Devices in terms of Polymerization Performance. The comparison of the obtained values of Depth of Cure shows that the depths of Cure of SCANWAVE PEN are Substantially Equivalent to the Predicate Devices. In conclusion, the results of the comparison show that SCANWAVE PEN and the Predicate Devices are Substantially Equivalent in performance of polymerization point of view.

Specific standard for Dental Curing Lights:

Also, SCANWAVE PEN has been tested according to a specific standard (Specification No 48) which defines the irradiance level per spectral domain. The results demonstrate that SCANWAVE PEN is compliant to the applicable standard for Dental Curing Lights.

11-e. Discussion and conclusion of the clinical Tests

Clinical tests are not required to establish the Substantial Equivalence.

12 - Conclusion

SCANWAVE PEN is Substantially Equivalent to the Predicate Devices (K072181, cleared September 19, 2007 and K091020, cleared June 12, 2009).

End of Section

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 11, 2014

Satelec-Acteon Group
Rick Rosati
Quality Manager
124 Gaither Drive, Suite 140
Mt. Laurel, NJ 08054

Re: K131906
Trade/Device Name: Scanwave pen (with light gray cord), Scanwave pen (with medium gray cord), Scanwave pen (with dark gray cord)
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: March 10, 2014
Received: March 11, 2014

Dear Mr. Rosati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 005 – Indication for Use

Indications for Use

510(k) Number (if known): K131906

Device Name: SCANWAVE PEN

Indications for Use:

SCANWAVE PEN is a source of illumination for the polymerization of light-curing dental materials curing in the wavelength range of 390 nm - 505 nm.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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